CInMED
Institut za ljekove i medicinska sredstva Crne Gore
Institute for Medicines and Medical Devices of Montenegro

INSTRUCTION ON THE MANNER OF SUBMITTING ADR REPORT

When submitting reports of adverse reactions to medicines, please ensure that the instructions listed below are followed, so the reports could be received and filed in an appropriate manner:

1. Report (fulfilled on the form of the Institute for medicines and medical devices, or on CIOMS form) must be accompanied by appropriate **cover letter** and electronic report (E2B format) on a CD. Cover letter shall be signed by a responsible person for pharmacovigilance in Montenegro, or in case of his/her unavailability, by a back-up responsible person, if the information on the appointment of a back-up is submitted to the Institute.
2. If E2B report may not be submitted within a legal deadline forseen for submission of reports to the Institute (15 days for serious and 90 days for non-serious adverse reactions) then E2B report is submitted afterwards, with the reference number under which previously submitted report was filed (fulfilled on the form of the Institute or on CIOMS form)
3. Cover letter should clearly state name of the case, i.e. brand **name of suspected medicine** and **name of a company** submitting the report
4. Cover letter should clearly state whether **initial** (first) or ***follow-up*** report is in question
5. If the *follow-up* report is in question, cover letter should state ***follow-up* report number** (first *follow-up* report, second *follow-up* report...) and also **name** and **reference number of initial report** that *follow-up* report refers to
6. Cover letter should state the source of the report (**spontaneous** report, or the report from **non-interventional study/literature/other**) and the information on the primary reporter for medically confirmed reports. If the report from a study is in question, cover letter should also state the exact **name of the study**
7. In exceptional cases only (such as reporting of suspected serious unexpected adverse reaction to medicines), a person responsible for pharmacovigilance in Montenegro, may submit the report via e-mail outside of working hours of the Institute which must be followed by submitting the report in the Office of the Institute
8. Reports which marketing authorisation holder/applicant for obtaining the authorization for the medicine receives from CInMED on the form of the Institute, are not required to be submitted on CIOMS form, or in E2B format, **except at the request of the Institute**.
9. Reporting of cases of adverse reactions to medicines that are described in local and international medical literature is done within time limits and on the manner prescribed by the local legislation and this instruction. Marketing authorisation holders in Montenegro are obliged to browse and continually follow **local and international medical literature**, as a significant source of information on safety of medicines, including also relevant published works/abstracts from scientifics and expert meetings. Marketing authorisation holder shall, along with the cover letter and generated report (completed on the form of the Institute, or CIOMS form), submit an electronic report (E2B format) and **published work** (if it is available to the marketing authorisation holder).